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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,742	12/28/2001	James G. Karras	ISPH-0623	8407
26259	7590	08/30/2004	EXAMINER	
LICATLA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			GIBBS, TERRA C	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 08/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/033,742

Applicant(s)

KARRAS ET AL.

Examiner

Terra C. Gibbs

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-10 and 12-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 12-14 is/are rejected.
- 7) ☒ Claim(s) 4-8 and 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Sequence search alignment.

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 24, 2004 has been entered.

Claims 3, 11, and 15-20 have been canceled. Claim 1 has been amended.

Claims 1, 2, 4-10, and 12-14 have been examined on the merits.

Response to Amendment

Applicants Amendment filed June 24, 2004 has been considered. Rejections and/or objections not reiterated from the previous office action mailed February 23, 2004 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "said antisense oligonucleotide" in line 6. There is insufficient antecedent basis for this limitation in the claim because the preamble of the claims refers to a compound, not an antisense oligonucleotide.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 12, 13, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Kool et al. [U.S. Patent No. 5,683,874].

Claim 1 is drawn to a compound 8 to 50 nucleobases in length targeted to nucleobases 361 through 425 of a 3'-untranslated region of a nucleic acid molecule encoding macrophage inflammatory protein 3-alpha (SEQ ID NO:3), wherein said compound specifically hybridizes with said region and inhibits the expression of macrophage inflammatory protein 3-alpha. Claims 2, 12, 13, and 14 are dependent on claim 1 and include all the limitations of claim 1, with the further limitations, wherein the compound is an antisense oligonucleotide, a composition

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comprising the compound of claim 1 and a pharmaceutically acceptable carrier or diluent, further comprising a colloidal dispersion system, wherein the composition is an antisense oligonucleotide.

Kool et al. disclose a linear oligonucleotide of the following sequence: 5'-CTTTCTTTTCTT-3' (SEQ ID NO:10) see Figure 2A. This linear oligonucleotide is reverse complementary to nucleobases 388-389 of SEQ ID NO:3 of the instant invention. It is noted that the reverse complementarity between the linear oligonucleotide disclosed by Kool et al. and nucleobases 388-389 of SEQ ID NO:3 is not contiguous, as the local similarity is almost 92% as it contains one mismatch (see attached sequence search alignment). Given this high degree of similarity, the linear oligonucleotide disclosed by Kool et al. meets all the structural requirements of the instant claims and would be expected to specifically hybridize to a nucleic acid encoding macrophage inflammatory protein 3-alpha, as per applicant's definition set forth in the specification as filed, pages 15 and 16, lines 27-31 and 1-14, respectively. Accordingly, the linear oligonucleotide disclosed by Kool et al. would specifically hybridize to SEQ ID NO:3 as claimed.

The burden of establishing whether the prior art oligonucleotide has the further function of inhibiting gene expression under generally any assay conditions falls to Applicant. See MPEP 2112.01, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the

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burden of showing that they are not.” In *re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In *re Best*, 562 F.2d at 1255, 195 USPQ at 433.” See also MPEP 2112: “[T]he PTO can require an Applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [her] claimed product.” The MPEP at 2112 citing *In re Fitzgerald* 205 USPQ 594, 596, (CCPA 1980), quoting *In re Best* 195 USPQ 430 as per above. Therefore, it falls to Applicant to determine and provide evidence that the linear oligonucleotide disclosed by Kool et al. would or would not have the additional functional limitation of “inhibiting expression” of macrophage inflammatory protein 3-alpha under generally any assay conditions.

Therefore, absent evidence to the contrary, claims 1, 2, 12, 13, and 14 are anticipated by Kool et al.

Claims 1, 2, 12, 13, and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Landsdorp et al. [U.S. Patent No. 6,514,693].

Landsdorp et al. disclose a hybridization probe of the following sequence: 5'-CCATTCCATTCCATT-3' (SEQ ID NO:5) see column 8, lines 23. This hybridization probe is reverse complementary to nucleobases 365-377 of SEQ ID NO:3 of the instant invention. It is noted that the reverse complementarity between hybridization probe disclosed by Landsdorp et al. and nucleobases 365-377 of SEQ ID NO:3 is not contiguous, as the local similarity is 92% as it contains one mismatch (see attached sequence search alignment). Given this high degree of similarity, the hybridization probe disclosed by Landsdorp et al. meets all the structural

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requirements of the instant claims and would be expected to specifically hybridize to a nucleic acid encoding macrophage inflammatory protein 3-alpha, as per applicant's definition set forth in the specification as filed, pages 15 and 16, lines 27-31 and 1-14, respectively. Accordingly, the hybridization probe disclosed by Landsdorp et al. would specifically hybridize to SEQ ID NO:3 as claimed.

The burden of establishing whether the prior art oligonucleotide has the further function of inhibiting gene expression under generally any assay conditions falls to Applicant. See MPEP 2112.01, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433." See also MPEP 2112: "[T]he PTO can require an Applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [her] claimed product." The MPEP at 2112 citing *In re Fitzgerald* 205 USPQ 594, 596, (CCPA 1980), quoting *In re Best* 195 USPQ 430 as per above. Therefore, it falls to Applicant to determine and provide evidence that the hybridization probe disclosed by Landsdorp et al. would or would not have the additional functional limitation of "inhibiting expression" of macrophage inflammatory protein 3-alpha under generally any assay conditions.

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Therefore, absent evidence to the contrary, claims 1, 2, 12, 13, and 14 are anticipated by Landsdorp et al.

Conclusion

Claims 4-8 and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is (571) 272-0758. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tcg
August 24, 2004

JOHN L. LEGUYADER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Sequence search alignment...

RESULT 27
US-08-413-813-10/c
; Sequence 10, Application US/08413813
; Patent No. 5683874
; GENERAL INFORMATION:
; APPLICANT: Kool, Eric T.
; TITLE OF INVENTION: SINGLE-STRANDED, CIRCULAR OLIGONUCLEOTIDES
; NUMBER OF SEQUENCES: 44
; CORRESPONDENCE ADDRESS:
; ADDRESSEE: Scully, Scott, Murphy & Presser
; STREET: 400 Garden City Plaza
; CITY: Garden City
; STATE: New York
; COUNTRY: USA
; ZIP: 11530
; COMPUTER READABLE FORM:
; MEDIUM TYPE: Floppy disk
; COMPUTER: IBM PC compatible
; OPERATING SYSTEM: PC-DOS/MS-DOS
; SOFTWARE: PatentIn Release #1.0, Version #1.25
; CURRENT APPLICATION DATA:
; APPLICATION NUMBER: US/08/413,813
; FILING DATE:
; CLASSIFICATION: 536
; ATTORNEY/AGENT INFORMATION:
; NAME: DiGiglio, Frank S.
; REGISTRATION NUMBER: 31,346
; REFERENCE/DOCKET NUMBER: 8085ZYX
; TELECOMMUNICATION INFORMATION:
; TELEPHONE: (516) 742-4343
; TELEFAX: (516) 742-4366

; TELEX: 230 901 SANS UR
; INFORMATION FOR SEQ ID NO: 10:
; SEQUENCE CHARACTERISTICS:
; LENGTH: 12 base pairs
; TYPE: nucleic acid
; STRANDEDNESS: single
; TOPOLOGY: linear
US-08-413-813-10

Query Match 16.0%; Score 10.4; DB 1; Length 12;
Best Local Similarity 91.7%; Pred. No. 32;
Matches 11; Conservative 0; Mismatches 1; Indels 0; Gaps 0;

Qy 28 AAGAACAGAAAG 39
||||| |||||
Db 12 AAGAAAGAAAG 1

Sequence Search alignment...

RESULT 12
US-08-730-635-5/c
Sequence 5, Application US/08730635
Patent No. 6514693
GENERAL INFORMATION:
APPLICANT: Lansdorp, Peter
TITLE OF INVENTION: Method for Detecting Multiple Copies of
TITLE OF INVENTION: a Repeat Sequence in a Nucleic Acid Molecule
Patent No. 6514693
NUMBER OF SEQUENCES: 14
CORRESPONDENCE ADDRESS:
ADDRESSEE: HOWSON & HOWSON
STREET: 321 No. 6514693ristown Road
CITY: Spring House
STATE: PA
COUNTRY: U.S.A.
ZIP: 19477
COMPUTER READABLE FORM:
MEDIUM TYPE: Floppy disk
COMPUTER: IBM PC compatible
OPERATING SYSTEM: PC-DOS/MS-DOS
SOFTWARE: PatentIn Release #1.0, Version #1.30
CURRENT APPLICATION DATA:
APPLICATION NUMBER: US/08/730,635
FILING DATE: 11-OCT-1996
CLASSIFICATION: 435
ATTORNEY/AGENT INFORMATION:
NAME: Bak, Mary E.
REGISTRATION NUMBER: 31,215
REFERENCE/DOCKET NUMBER: B&P7USA
TELECOMMUNICATION INFORMATION:
TELEPHONE: (215) 540-9200
TELEFAX: (215) 540-5818
TELEX: N/A
INFORMATION FOR SEQ ID NO: 5:
SEQUENCE CHARACTERISTICS:
LENGTH: 15 base pairs
TYPE: nucleic acid
STRANDEDNESS: single
TOPOLOGY: linear

MOLECULE TYPE: DNA (genomic)
US-08-730-635-5

Query Match 17.5%; Score 11.4; DB 1; Length 15;
Best Local Similarity 92.3%; Pred. No. 23;
Matches 12; Conservative 0; Mismatches 1; Indels 0; Gaps 0;

QY 5 TGGAAATGGAATTG 17
|||||
Db 13 TGGAAATGGAATGG 1